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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/520,489	03/08/2000	Jurg Tschopp	A049 US	1565

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EXAMINER

CANELLA, KAREN A

ART UNIT PAPER NUMBER

1642

DATE MAILED: 09/26/2002

13

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/520,489

Applicant(s)
Tschopp

Examiner
Karen Canella

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1642



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 months MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on _____
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 36, 39-46, 48, and 49 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 36, 39-46, 48, and 49 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other:

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DETAILED ACTION

1. After review and reconsideration, the finality of the Office action of Paper No. 8 is withdrawn.
2. Claims 37 and 47 have been canceled. Claims 36, 39, 40, 41, 42, 43, 44 and 45 have been amended. Claims 36, 39-46, 48 and 49 are pending and under consideration.

New Grounds of Rejection

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

4. Claims 36 and 39-45 are rejected under 35 U.S.C. 102(e) as being anticipated by Wiley (U.S. 6,171,787).

Claim 36 is drawn to a method of treating, suppressing or altering the progression of a cancer comprising administering to a patient an effective amount of an antibody directed against an APRIL ligand polypeptide and an APRIL receptor. Claim 39 embodies the method of claim 36 wherein said antibody is administered to said patient in combination with a chemotherapeutic agent. Claim 40 embodies the method of claim 36 wherein said antibody is administered to said

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patient in combination with radiation therapy. Claim 41 is drawn to a method of suppressing growth of a tumor cell that expresses the APRIL ligand polypeptide of SEQ ID NO:2, comprising the step of contacting said cell with an effective amount of an antibody which specifically binds to the APRIL ligand of SEQ ID NO:2 and an antibody which specifically binds to said APRIL ligand polypeptide, and blocks the interaction between said APRIL polypeptide and receptor and an antibody which binds to a soluble APRIL ligand polypeptide. Claim 42 is drawn to a method of suppressing growth of a tumor cell that expresses the APRIL receptor polypeptide, comprising the step of contacting said cell with an effective amount of an agent selected from the group consisting of an antibody which specifically binds to the APRIL ligand polypeptide; an antibody which specifically binds to a soluble APRIL ligand polypeptide, an antibody which specifically binds to an APRIL ligand polypeptide consisting of residues 157 to 250 of SEQ ID NO:2; and an antibody which specifically binds to said APRIL ligand polypeptide, and blocks the interaction between said APRIL polypeptide and receptor. Claim 43 is drawn to method for treating cancer comprising administration of a therapeutically effective amount of a pharmaceutical composition comprising a pharmaceutically acceptable carrier and a therapeutically effective amount of an antibody directed to an APRIL ligand polypeptide capable of interfering with the interaction between said APRIL ligand polypeptide and an APRIL receptor.. Claim 44 is drawn to a method of suppressing growth of a tumor cell that expressed APRIL ligand polypeptide comprising the step of exposing said cell to an effective amount of an antibody directed to the APRIL ligand polypeptide capable of interfering with an interaction between said APRIL ligand polypeptide and an APRIL receptor. Claim 45 is drawn to a method for suppressing growth of a tumor cell that expressed APRIL receptor polypeptide comprising the step of exposing said cell to an effective amount of an antibody directed to the APRIL receptor polypeptide capable of interfering with an interaction between said APRIL ligand polypeptide and an APRIL receptor.

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Wiley discloses the instant SEQ ID NO:2 as human TNF gamma (SEQ ID NO:2) (column 6, lines 41-42) as well as soluble human TNF-gamma (SEQ ID NO:3), (column 57, lines 27-28). Wiley discloses that antibodies, antagonists and inhibitors of TNF-gamma polypeptide may be used to treat tumors or metastasis (abstract), and that these agents can be combined with radiotherapy of other chemotherapeutic agents (column 24, lines 48-52). Wiley discloses that TNF-gamma antibodies, TNF-gamma receptor antagonists or combinations thereof may be combined with pharmaceutically acceptable excipients to form therapeutic compositions (page 25, lines 16-21). Wiley discloses the production of antibodies to TNF-gamma receptor (column 33, lines 18-21). Wiley discloses the immunization of animals with the soluble TNF-gamma of SEQ ID NO:3 (column 58, lines 59-61). Wiley discloses a method of treating conditions associated with altered or abnormal expression of TNF-gamma comprising the administration of an antibody which binds to TNF-gamma (column 18, lines 20-23). Wiley discloses that antagonists can be antibodies (column 36, lines 29-30) and that antagonists of TNF-gamma block the inhibitory effects of TNF-gamma and promote angiogenesis (column 32, lines 24-26) which would be conducive to the destruction of metastatic cancer (column 25, lines 49-54).

5. Claims 46, 48 and 49 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.. The claims recite "polypeptide encoded by SEQ ID NO:2". However, SEQ ID NO:2 is a polypeptide not a polynucleotide.

6. All other rejections and objections as stated in Paper No. 8 are withdrawn.

Conclusion

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen Canella whose telephone number is (703) 308-8362. The examiner

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can normally be reached on Monday through Friday from 8:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached on (703) 308-3995. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Karen A. Canella, Ph.D.

Patent Examiner, Group 1642

September 13, 2002


ANTHONY C. CAPUTA
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